Sample Management and Biosafety Guidelines for Handling Samples or Materials Associated with SARS CoV2 (COVID-19)

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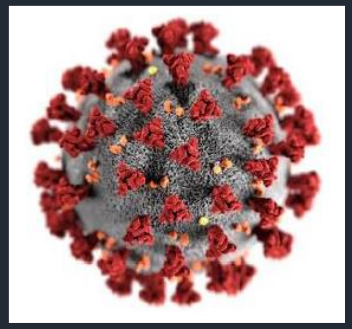

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Today's presentation

- SARS CoV2/COVID-19 sample management
  - sample collection, shipment and storage
- Biosafety guidance on COVID-19 biosafety
- Questions

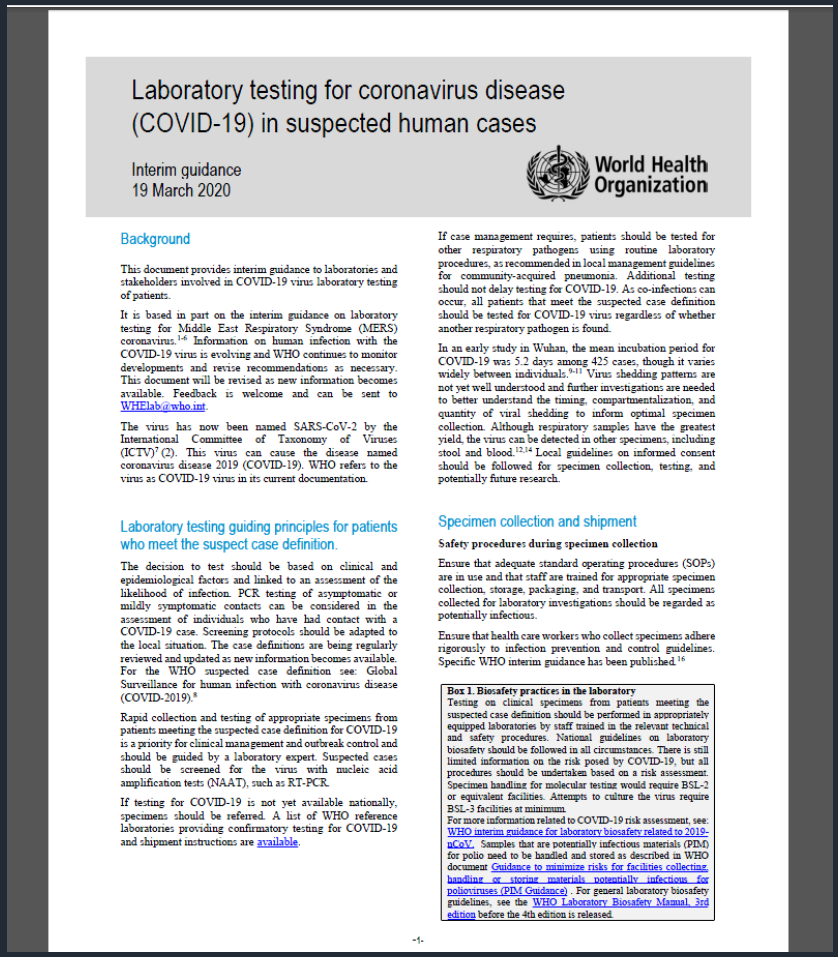
Overview of Sample Management

- Sample management is a part of process control, one of the essentials of a quality management system.
- The quality of the work a laboratory produces is only as good as the quality of the samples it uses for testing.
- The laboratory must be proactive in ensuring that the samples it receives meet all of the requirements needed to produce accurate test results.
- Sample management components
  - information needed on requisitions or forms
  - handling urgent requests
  - collection, labeling, preservation and transport
  - safety practices (leaking or broken containers, contaminated forms, other biohazards)
  - evaluating, processing, and tracking samples
  - storage, retention, and disposal.

Interim WHO guidance:

Laboratory testing for COVID-19

https://apps.who.int/iris/bitstream/handle/10665/331501/WHO-COVID-19-laboratory-2020.5-eng.pdf?sequence=1&isAllowed=y



Laboratory testing for coronavirus disease (COVID-19) in suspected human cases

Interim guidance
19 March 2020

World Health Organization

Background

This document provides interim guidance to laboratories and stakeholders involved in COVID-19 virus laboratory testing of patients.

It is based in part on the interim guidance on laboratory testing for Middle East Respiratory Syndrome (MERS) coronavirus.[1-6] Information on human infection with the COVID-19 virus is evolving and WHO continues to monitor developments and revise recommendations as necessary. This document will be revised as new information becomes available. Feedback is welcome and can be sent to WHElab@who.int.

The virus has now been named SARS-CoV-2 by the International Committee of Taxonomy of Viruses (ICTV)[7] (2). This virus can cause the disease named coronavirus disease 2019 (COVID-19). WHO refers to the virus as COVID-19 virus in its current documentation.

Laboratory testing guiding principles for patients who meet the suspect case definition.

The decision to test should be based on clinical and epidemiological factors and linked to an assessment of the likelihood of infection. PCR testing of asymptomatic or mildly symptomatic contacts can be considered in the assessment of individuals who have had contact with a COVID-19 case. Screening protocols should be adapted to the local situation. The case definitions are being regularly reviewed and updated as new information becomes available. For the WHO suspected case definition see: Global Surveillance for human infection with coronavirus disease (COVID-2019).[8]

Rapid collection and testing of appropriate specimens from patients meeting the suspected case definition for COVID-19 is a priority for clinical management and outbreak control and should be guided by a laboratory expert. Suspected cases should be screened for the virus with nucleic acid amplification tests (NAAT), such as RT-PCR.

If testing for COVID-19 is not yet available nationally, specimens should be referred. A list of WHO reference laboratories providing confirmatory testing for COVID-19 and shipment instructions are available.

If case management requires, patients should be tested for other respiratory pathogens using routine laboratory procedures, as recommended in local management guidelines for community-acquired pneumonia. Additional testing should not delay testing for COVID-19. As co-infections can occur, all patients that meet the suspected case definition should be tested for COVID-19 virus regardless of whether another respiratory pathogen is found.

In an early study in Wuhan, the mean incubation period for COVID-19 was 5.2 days among 425 cases, though it varies widely between individuals.[9-11] Virus shedding patterns are not yet well understood and further investigations are needed to better understand the timing, compartmentalization, and quantity of viral shedding to inform optimal specimen collection. Although respiratory samples have the greatest yield, the virus can be detected in other specimens, including stool and blood.[12,14] Local guidelines on informed consent should be followed for specimen collection, testing, and potentially future research.

Specimen collection and shipment

Safety procedures during specimen collection

Ensure that adequate standard operating procedures (SOPs) are in use and that staff are trained for appropriate specimen collection, storage, packaging, and transport. All specimens collected for laboratory investigations should be regarded as potentially infectious.

Ensure that health care workers who collect specimens adhere rigorously to infection prevention and control guidelines. Specific WHO interim guidance has been published.[16]

Box 1. Biosafety practices in the laboratory

Testing on clinical specimens from patients meeting the suspected case definition should be performed in appropriately equipped laboratories by staff trained in the relevant technical and safety procedures. National guidelines on laboratory biosafety should be followed in all circumstances. There is still limited information on the risk posed by COVID-19, but all procedures should be undertaken based on a risk assessment. Specimen handling for molecular testing would require BSL-2 or equivalent facilities. Attempts to culture the virus require BSL-3 facilities at minimum.
For more information related to COVID-19 risk assessment, see: WHO interim guidance for laboratory biosafety related to 2019-nCoV. Samples that are potentially infectious materials (PIM) for polio need to be handled and stored as described in WHO document Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance) . For general laboratory biosafety guidelines, see the WHO Laboratory Biosafety Manual, 3rd edition before the 4th edition is released.

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Laboratory testing for COVID-19

- Nucleic acid amplification tests (NAAT)
- Rapid Antigen detection
- Serological testing
  - **Rapid diagnostic test (RDT)**
  - **ELISA**
  - **Neutralization assay**
  - **Chemiluminescent immunoassay**
- Viral sequencing
- Viral culture

Specimens to be collected from symptomatic patients and contacts

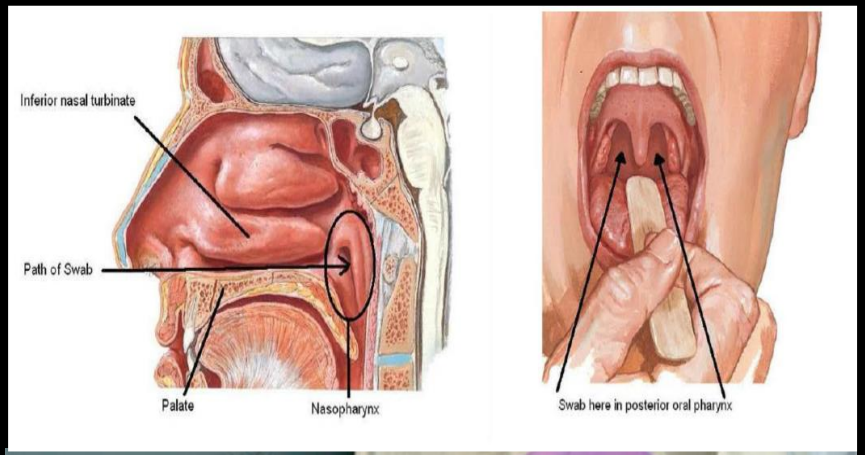
	Test	Type of sample	Timing
Patient	NAAT	Lower respiratory tract - sputum - aspirate - lavage Upper respiratory tract - nasopharyngeal and - oropharyngeal swabs - nasopharyngeal wash/nasopharyngeal aspirate. Consider stools, whole blood, urine, and if diseased, material from autopsy.	Collect on presentation. Possibly repeated sampling to monitor clearance. Further research needed to determine effectiveness and reliability of repeated sampling.
Patient	Serology	Serum for serological testing once validated and available.	Paired samples are necessary for confirmation with the initial sample collected in the first week of illness and the second ideally collected 2-4 weeks later (optimal timing for convalescent sample needs to be established).
Contact in health-care centre associated outbreaks or other settings where contacts have symptoms, or where asymptomatic contacts have had high-intensity contact with a COVID-19 case.	NAAT	Nasopharyngeal and oropharyngeal swabs.	Within incubation period of last documented contact.
	Serology	Serum for serological testing once validated and available.	Baseline serum taken as early as possible within incubation period of contact and convalescent serum taken 2-4 weeks after last contact (optimal timing for convalescent sample needs to be established).

Specimen collection and shipment

Specimen type	Collection materials	Storage temperature until testing in-country laboratory	Recommended temperature for shipment according to expected shipment time
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocked swabs*	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Bronchoalveolar lavage	Sterile container *	2-8 °C	2-8 °C if ≤2 days –70 °C (dry ice) if >2 days
(Endo)tracheal aspirate, nasopharyngeal or nasal wash/aspirate	Sterile container *	2-8 °C	2-8 °C if ≤2 days –70 °C (dry ice) if >2 days
Sputum	Sterile container	2-8 °C	2-8 °C if ≤2 days –70 °C (dry ice) if >2 days
Tissue from biopsy or autopsy including from lung.	Sterile container with saline or VTM.	2-8 °C	2-8 °C if ≤24 hours –70 °C (dry ice) if >24 hours
Serum	Serum separator tubes (adults: collect 3-5 ml whole blood).	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Whole blood	Collection tube	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Stool	Stool container	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Urine	Urine collection container	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days

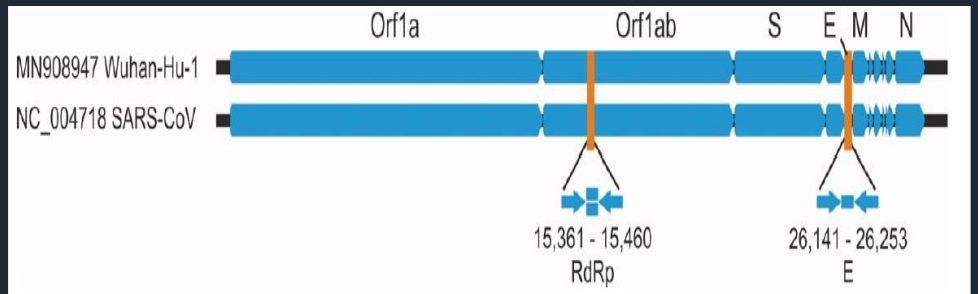
* For transport of samples for viral detection, use viral transport medium (VTM) containing antifungal and antibiotic supplements. Avoid repeated freezing and thawing of specimens. If VTM is not available sterile saline may be used instead (in which case, duration of sample storage at 2-8 °C may be different from what is indicated above).

Specimen Collection
Swab Specimen Collection



Nucleic acid amplification tests (NAAT) for COVID-19 virus

- Routine confirmation of cases of COVID-19 is based on detection of unique sequences of virus RNA by NAAT
- real-time reverse-transcription polymerase chain reaction (rRT-PCR) with confirmation by nucleic acid sequencing when necessary.
- The viral genes targeted so far include the N, E, S and RdRP genes.
- RNA extraction should be done in a biosafety cabinet in a BSL-2 or equivalent facility.



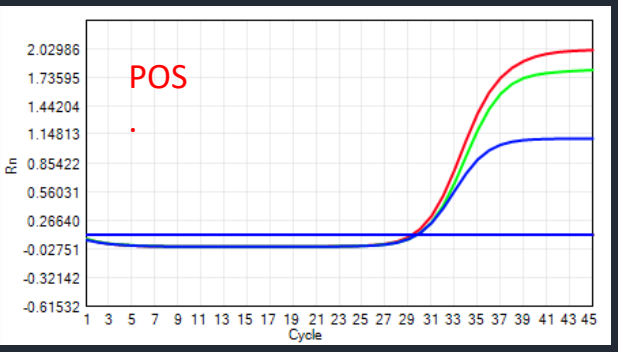
Institute	Gene targets
China CDC, China	ORF1ab and N
Institut Pasteur, Paris, France	Two targets in RdRP
US CDC, USA	Three targets in N gene
National Institute of Infectious Diseases, Japan	Pancorona and multiple targets, Spike protein
Charité, Germany	RdRP, E, N
HKU, Hong Kong SAR	ORF1b-nsp14, N
National Institute of Health, Thailand	N

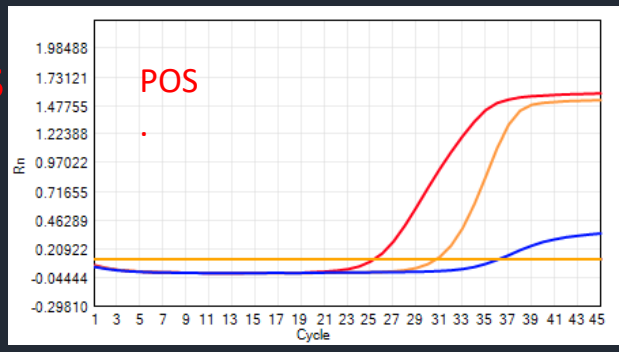
https://www.who.int/docs/default-source/coronaviruse/whoinhouseassays.pdf?sfvrsn=de3a76aa_2

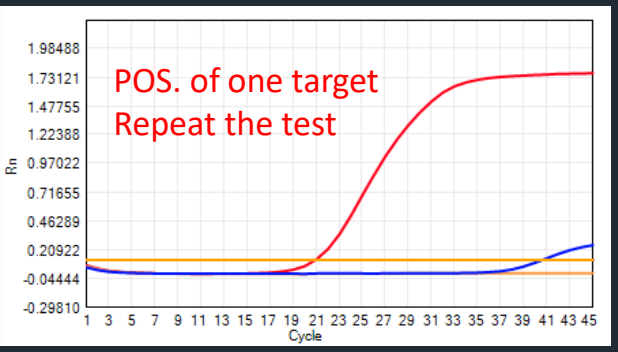
The sensitivities of the tests to individual genes are comparable according to comparison studies except the RdRpSARSr (Charité) primer probe, which has a slightly lower sensitivity likely due to a mismatch in the reverse primer

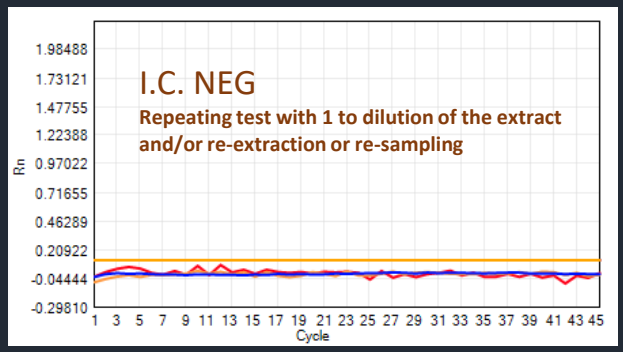
J Clin Microbiol. 2020;JCM.00557-20. Published online April 8, 2020. doi:10.1128/JCM. 00557-20

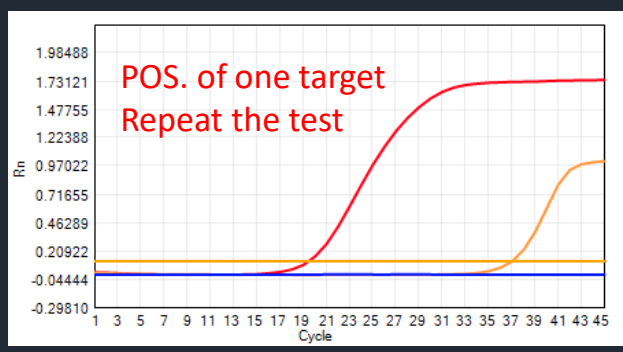
Interpreting rRT-PCR Tests

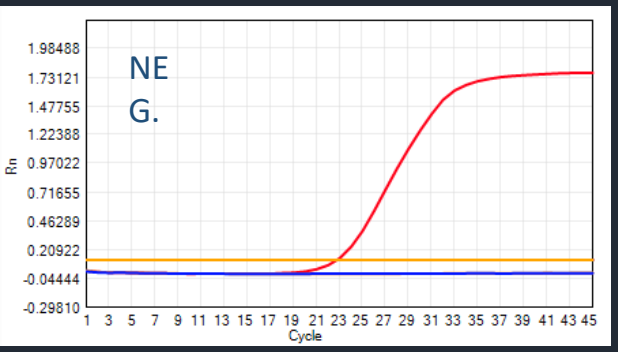


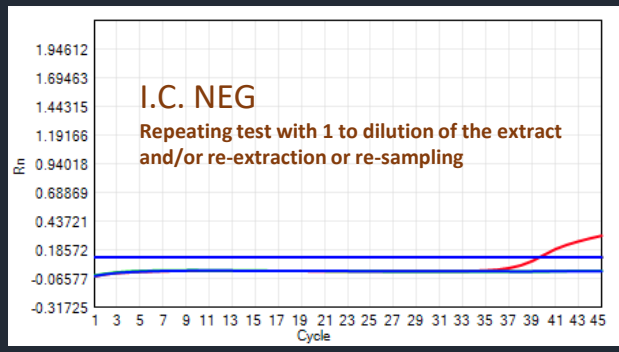












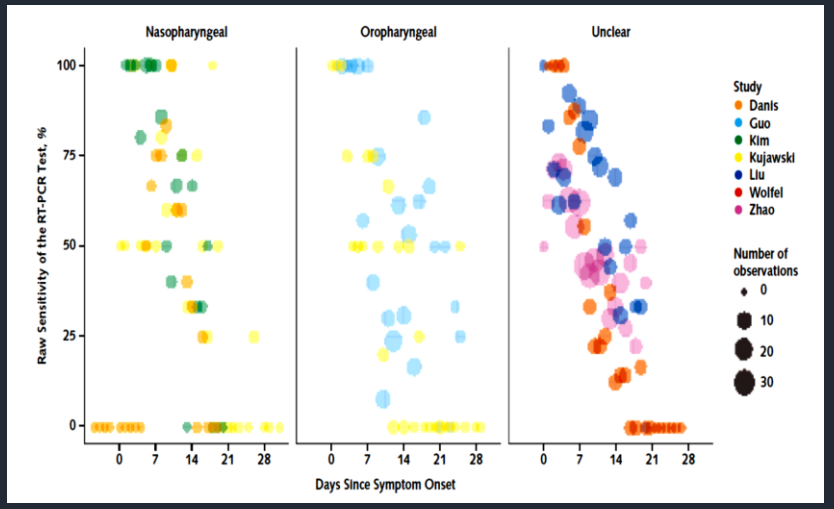
Detection of SARS-CoV-2 in different types of clinical specimens

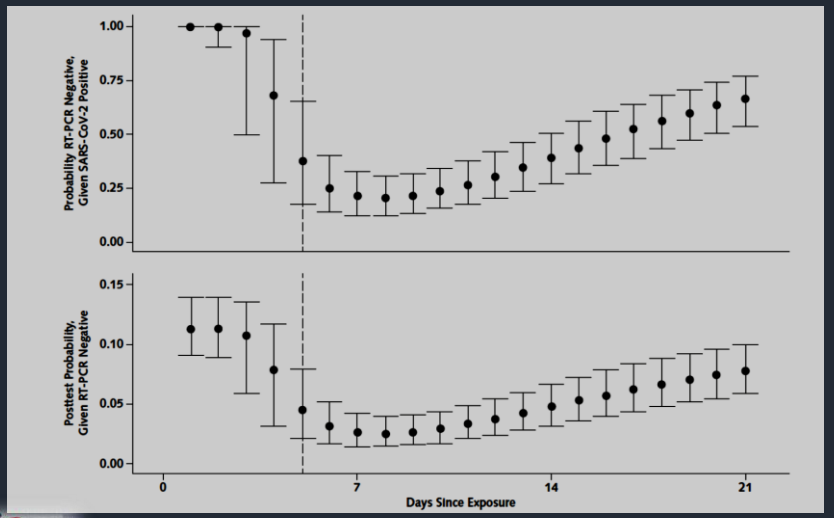
- data suggest the sensitivity of the COVID19 RT-PCR :
  - 32% for oropharyngeal,
  - 63% for nasopharyngeal (NP)
    - It was reported Pharyngeal washing has the same sensitivity ??
  - 73% for sputum samples
  - 93% for tracheal aspirates/ bronchoalveolar lavage (BAL)
  - Saliva ??
- False-negative results mainly occurred due to
  - inappropriate timing of sample collection in relation to illness onset
  - deficiency in sampling technique, especially of nasopharyngeal swabs.
- Specificity of most of the RT-PCR tests is 100%

JAMA. doi.org/10.1001/jama.2020.3786

False-Negative Rate of RT-PCR–Based SARS-CoV-2 Tests by Time Since Exposure

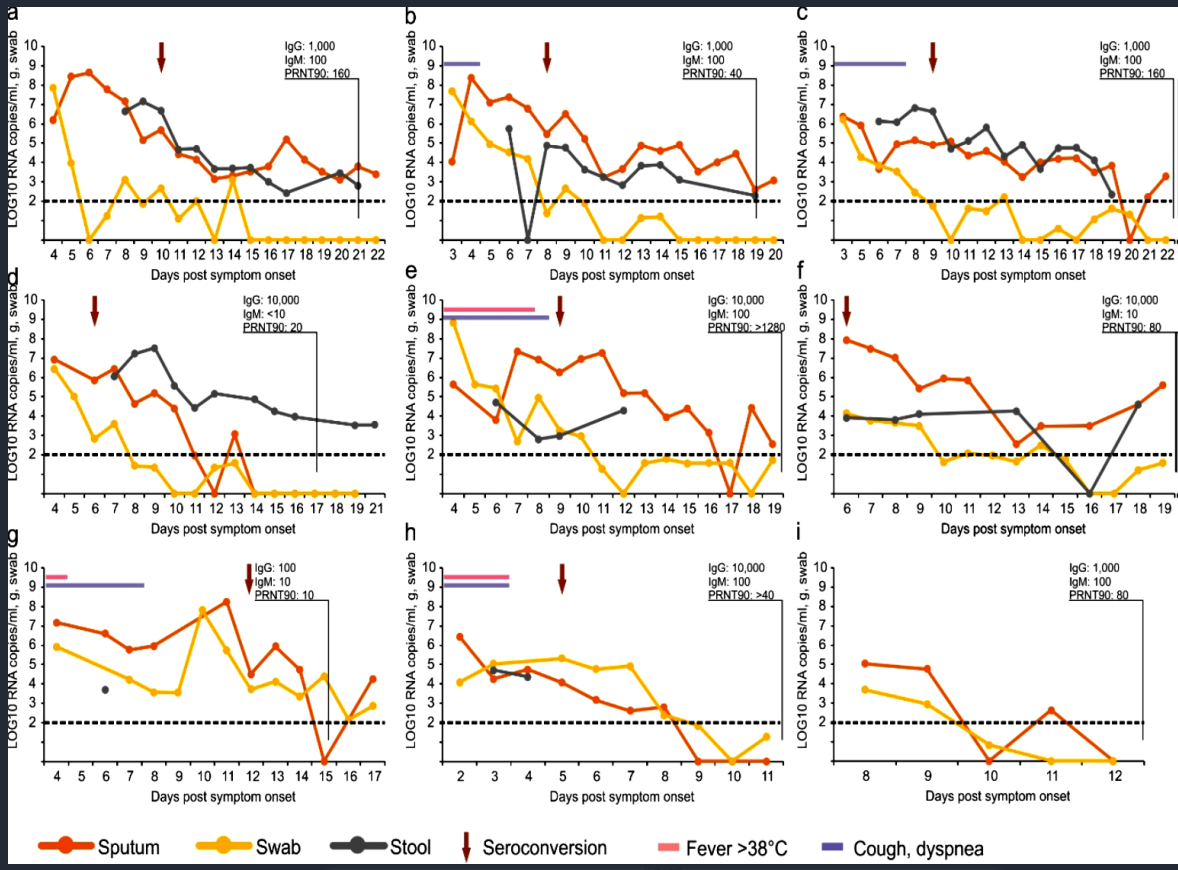
- Over the 4 days of infection before the typical time of symptom onset (day 5), the probability of a false-negative result in an infected person decreases from
  - 100% (95% CI, 100% to 100%) on day 1
  - 67% (CI, 27% to 94%) on day 4
- On the day of symptom onset, the median false-negative rate
  - 38% (CI, 18% to 65%) on day 5
  - decreased to 20% (CI, 12% to 30%) on day 8
  - then began to increase again, from 21% (CI, 13% to 31%) on day 9 to 66% (CI, 54% to 77%) on day 21.





Viral load kinetics, seroconversion and clinical observations in individual

- Pharyngeal virus shedding was very high during the first week of symptoms
  - peak at 7.11 X 10e+8 RNA copies / throat swab, day 4.
- Infectious virus was readily isolated from throat- and lung-derived samples, but not from stool samples in spite of high virus RNA concentration.
- Blood and urine never yielded virus.
- Shedding of viral RNA from sputum outlasted the end of symptoms.
- Seroconversion occurred after 6-12 days, but was not followed by a rapid decline of viral loads.
- Asymptomatic persons seem to shed virus longer than symptomatic ones and show weak immunologic reaction than to symptomatic one.



Nature 581, 465–469 (2020)

Serology-based tests for COVID-19

- Serology testing for SARS-CoV-2 is at increased demand in order to better quantify the number of cases of COVID-19
  - including those that may be asymptomatic or have recovered.
- Serology tests are blood-based tests
- be used to identify whether people have been exposed to SARSCoV-2
  - In contrast, the RT-PCR tests currently being used globally to diagnose cases of COVID-19 can only indicate the presence of viral material during infection and will not indicate if a person was infected and subsequently recovered.
- Serological diagnosis also is becoming an important tool to understand the extent of COVID-19 in the community and to identify individuals who are immune and potentially “protected” from becoming infected.

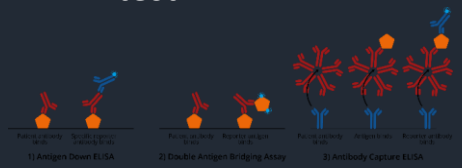
Description of types of serology assays

Rapid diagnostic test (RDT)

- a qualitative (positive or negative) lateral flow assay
- can be used at point of care (POC)

ELISA

- qualitative or quantitative
- generally a lab-based test
- most frequently test



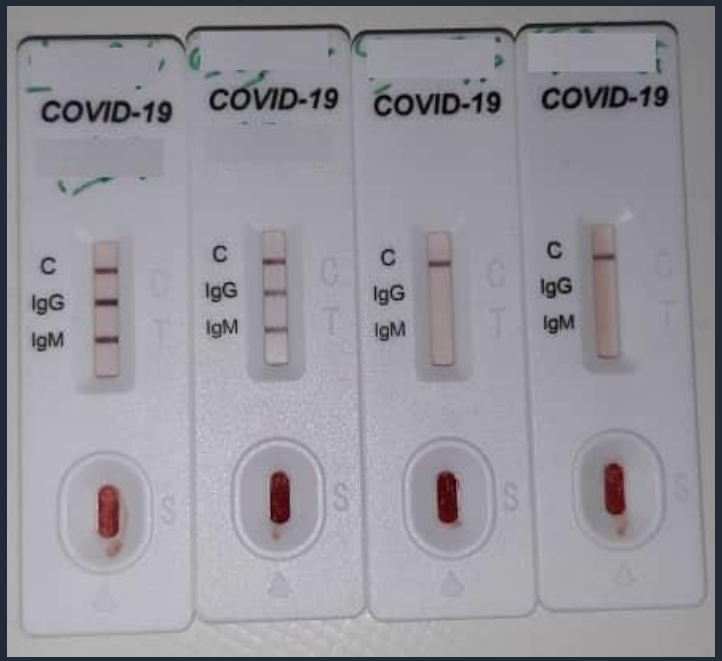
Neutralization assay

- This test relies on patient antibodies to prevent viral infection of cells in a lab setting
- Neutralization assays depend on cell culture, a lab-based method of culturing cells that allow SARS-CoV-2 growth (like VeroE6 cells)

Chemiluminescent immunoassay

- typically quantitative, lab-based
- uses whole blood, plasma, or serum samples from patients
- The test relies on mixing patient samples with a known viral protein, buffer reagents, and specific enzyme-labeled antibodies that allow a light-based, luminescent read-out.

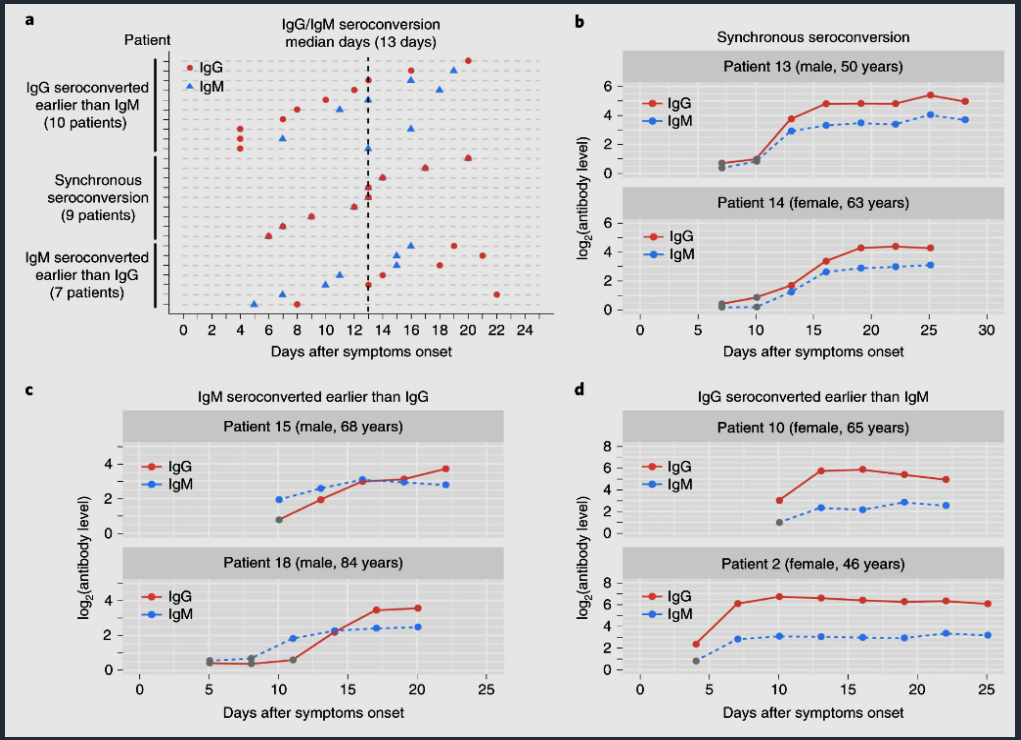
Type of test	Time to results	What it tells us	What it cannot tell us
Rapid diagnostic test (RDT)	10-30 minutes	The presence or absence (qualitative) of antibodies against the virus present in patient serum.	The amount of antibodies in the patient serum, or if these antibodies are able to inhibit virus growth
Enzyme linked immunosorbent assay (ELISA)	2-5 hours	The presence or absence (quantitative) of antibodies against the virus present in patient serum.	If the antibodies are able to inhibit virus growth.
Neutralization assay	3-5 days	The presence of active antibodies in patient serum that are able to inhibit virus growth *ex vivo*, in a cell culture system.	It may miss antibodies to viral proteins that are not involved in replication.
Chemiluminescent immunoassay	1-2 hours	The presence or absence (quantitative) of antibodies against the virus present in the patient serum.	If the antibodies are able to inhibit virus growth.



https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html#sec1

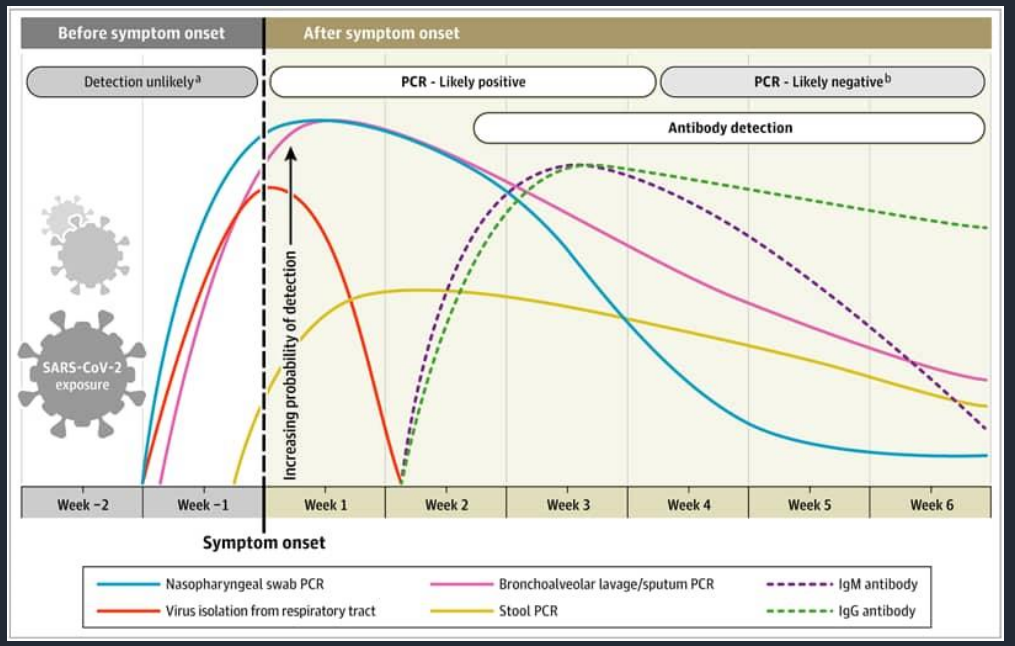
Antibody responses to SARS-CoV-2 in patients with COVID-19

- Within 19 days after symptom onset, 100% of patients tested positive for antiviral IgG.
- Seroconversion for IgG and IgM occurred simultaneously or sequentially.
- Both IgG and IgM titers plateaued within 6 days after seroconversion.



Interpreting Diagnostic Tests for SARS-CoV-2

- IgM and IgG seroconversion occurred in all patients between the third and fourth week of clinical illness onset.
- IgM begins to decline and reaches lower levels by week 5 and almost disappears by week 7.
- IgG persists beyond 7 weeks.
- combined sensitivity of PCR and IgM ELISA directed at nucleocapsid (NC) antigen was 98.6% vs 51.9% with a single PCR test.
  - During the first 5.5 days, quantitative PCR had a higher positivity rate than IgM
  - whereas IgM ELISA had a higher positivity rate after day 5.5 of illness
- majority of AbS are produced against the most abundant protein of the virus, which is the NC.
  - antibodies to NC would be the most sensitive.
- RBD-S protein is the host attachment protein, and antibodies to RBD-S would be more specific and are expected to be neutralizing
- cross-reactivity with SARS-CoV and possibly other coronaviruses

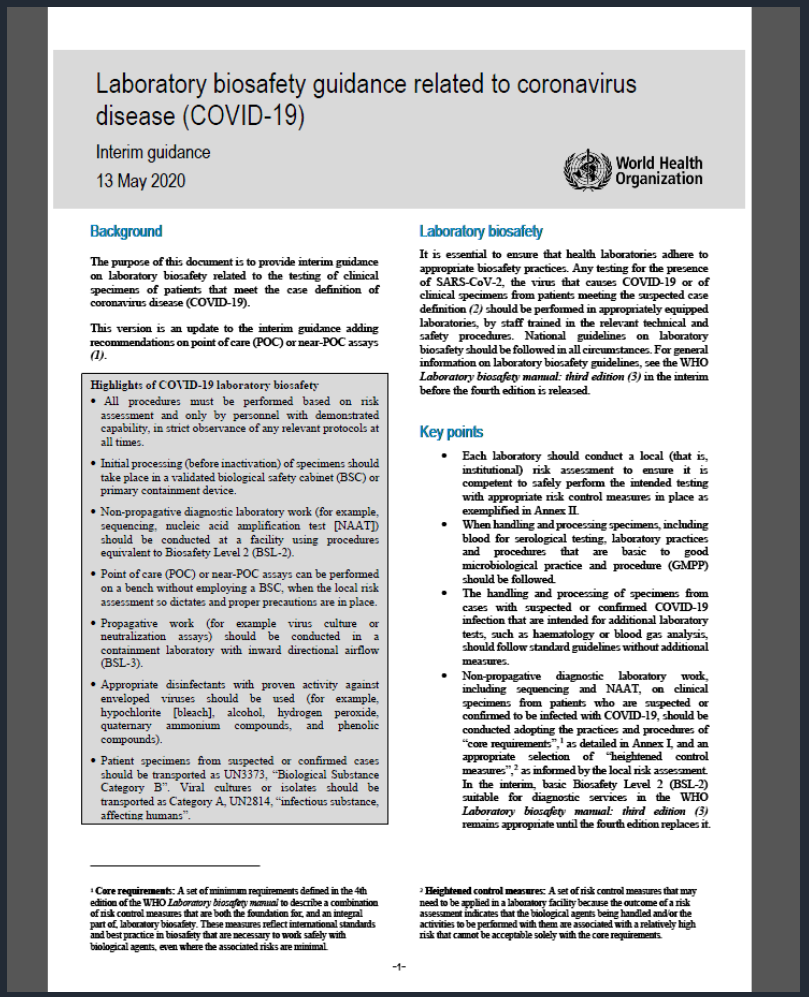


- Most of the available data are for adult populations who are not immunocompromised.
- The time course of PCR positivity and seroconversion may vary in children and other groups,
  - including the large population of asymptomatic individuals who go undiagnosed without active surveillance

JAMA. 2020;323(22):2249-2251.
Doi:10.1001/jama.2020.8259

WHO biosafety guidance

https://apps.who.int/iris/handle/10665/332076



Laboratory biosafety guidance related to coronavirus disease (COVID-19)

Interim guidance

13 May 2020

World Health Organization

Background

The purpose of this document is to provide interim guidance on laboratory biosafety related to the testing of clinical specimens of patients that meet the case definition of coronavirus disease (COVID-19).

This version is an update to the interim guidance adding recommendations on point of care (POC) or near-POC assays *(1)*.

Highlights of COVID-19 laboratory biosafety

- All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.
- Initial processing (before inactivation) of specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.
- Non-propagative diagnostic laboratory work (for example, sequencing, nucleic acid amplification test [NAAT]) should be conducted at a facility using procedures equivalent to Biosafety Level 2 (BSL-2).
- Point of care (POC) or near-POC assays can be performed on a bench without employing a BSC, when the local risk assessment so dictates and proper precautions are in place.
- Propagative work (for example virus culture or neutralization assays) should be conducted in a containment laboratory with inward directional airflow (BSL-3).
- Appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, hydrogen peroxide, quaternary ammonium compounds, and phenolic compounds).
- Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance Category B". Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans".

Laboratory biosafety

It is essential to ensure that health laboratories adhere to appropriate biosafety practices. Any testing for the presence of SARS-CoV-2, the virus that causes COVID-19 or of clinical specimens from patients meeting the suspected case definition *(2)* should be performed in appropriately equipped laboratories, by staff trained in the relevant technical and safety procedures. National guidelines on laboratory biosafety should be followed in all circumstances. For general information on laboratory biosafety guidelines, see the WHO *Laboratory biosafety manual: third edition (3)* in the interim before the fourth edition is released.

Key points

- Each laboratory should conduct a local (that is, institutional) risk assessment to ensure it is competent to safely perform the intended testing with appropriate risk control measures in place as exemplified in Annex II.
- When handling and processing specimens, including blood for serological testing, laboratory practices and procedures that are basic to good microbiological practice and procedure (GMPP) should be followed.
- The handling and processing of specimens from cases with suspected or confirmed COVID-19 infection that are intended for additional laboratory tests, such as haematology or blood gas analysis, should follow standard guidelines without additional measures.
- Non-propagative diagnostic laboratory work, including sequencing and NAAT, on clinical specimens from patients who are suspected or confirmed to be infected with COVID-19, should be conducted adopting the practices and procedures of "core requirements",[1] as detailed in Annex I, and an appropriate selection of "heightened control measures",[2] as informed by the local risk assessment. In the interim, basic Biosafety Level 2 (BSL-2) suitable for diagnostic services in the WHO *Laboratory biosafety manual: third edition (3)* remains appropriate until the fourth edition replaces it.

[1] **Core requirements:** A set of minimum requirements defined in the 4th edition of the WHO *Laboratory biosafety manual* to describe a combination of risk control measures that are both the foundation for, and an integral part of, laboratory biosafety. These measures reflect international standards and best practice in biosafety that are necessary to work safely with biological agents, even where the associated risks are minimal.

[2] **Heightened control measures:** A set of risk control measures that may need to be applied in a laboratory facility because the outcome of a risk assessment indicates that the biological agents being handled and/or the activities to be performed with them are associated with a relatively high risk that cannot be acceptable solely with the core requirements.

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Risk Assessment: COVID-19 hazard assessment clinical/lab procedures

Procedure	What could go wrong or hazard?	Overall risk
Whole-genome sequencing	• None	• None
SARS-CoV2 POCT	• Aerosol exposure during NA extraction • Eye splash during sample processing	• Low/Medium (Sample dependent)
Serology for SARS-CoV2	• Aerosol exposure during sample processing • Eye splash during sample processing	• Low • Medium
SARS-CoV2 RT-PCR	• Aerosol exposure during NA extraction	• Medium
Sample collection	• Aerosol exposure from patient during sample collection • Eye splash during sample processing	• High • Medium
Sample reception	• Leaking sample	• High
Virus isolation	• Aerosol exposure during sample processing • Eye splash during sample processing • Infectious culture material spill	• High • Medium • Medium/High

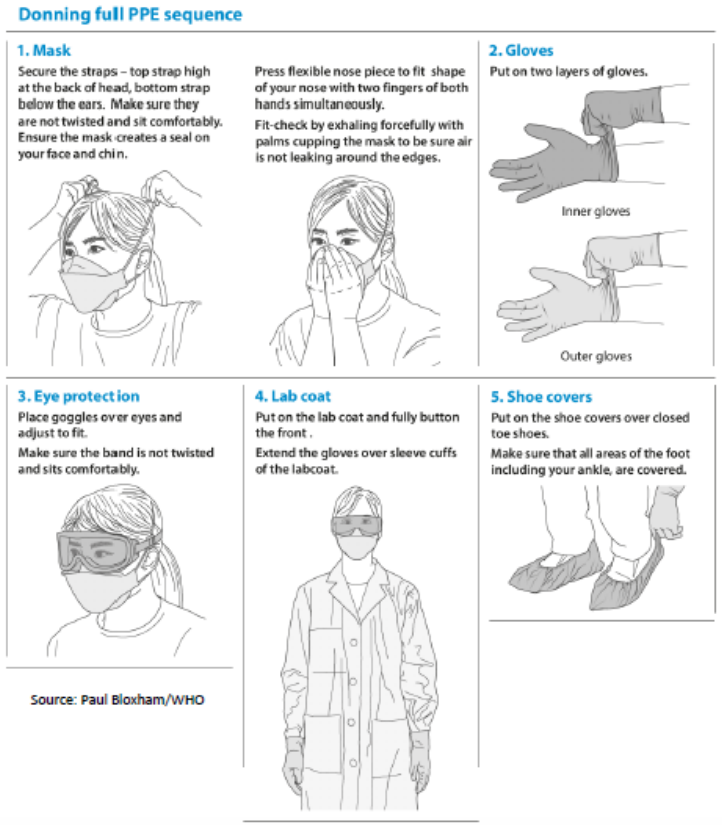
Risk Assessment: COVID-19 residual risk post-mitigation

Procedure	Risk approach	Risk mitigation	Residual risk
Sample collection SARS-CoV2 POCT Serological testing for SARS-CoV2	Core	Standard PPE + Respirator (if risk assessment indicates) GMPP Validated waste management Well-ventilated area	Low
Sample reception SARS-CoV2 RT-PCR	Core + Heightened control measures	BSL2 Work in BSC Standard PPE + Respirator (if risk assessment indicates) GMPP Validated waste management	Low
Virus isolation Note: This is a High Risk *activity - Only to be performed by reference labs with inward directional airflow*	Heightened control measures	Inward airflow laboratory Work in BSC Standard PPE + Respirator (if risk assessment indicates) GMPP Validated waste management	Low

- Standard PPE – Gown, gloves, eye protection, apron
- Respirator – N95 or similar, fit tested
- BSC – validated Biosafety cabinet
- PPE – Personal Protective Equipment
- GMPP – Good Microbiological Practices and Procedures

PPE for sample collection and most lab procedures for COVID-19

- Follow WHO guidance for steps of donning and doffing PPE.
- Use risk assessment for PPE choice (may include)
  - Lab coat
  - Gloves
  - Eye protection
  - Mask/respirator (risk assessment-based)
  - Shoe covers
- Change gloves between patient samples
- Perform hand hygiene before and after contact with the patient and their surroundings and after PPE removal.



Note: For illustration purposes – double gloves not recommended for SARS-CoV-2 testing

Source: Paul Bloxham/WHO


uvex
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Sample collection, identification and packing

2

Put a label on the VTM tube / cryovial / screw-capped container.

Using a permanent marker, write on the label:

- the patient's name,
- age, gender,
- date of onset of symptoms,
- type of sample
- date of sample collection.

3

After collecting the sample close the lid of the VTM tube /cryovial / screw-capped container and secure with parafilm.

Wipe with tissue soaked with 0.5% bleach solution (see How to make 0.5 bleach solution on pages 12 -13).

4

Wrap the whole VTM tube / cryovial / screw-capped container with tissue or absorbent material and seal with clear tape.

5

Using permanent marker draw an arrow on the tissue wrapped VTM tube / cryovial / screw-capped container to indicate top of the container and to ensure it is packed and handled in the upright position.

6

Put the VTM tube / cryovial / screw-capped container in the plastic zip lock bag and close the zip completely.

Make sure arrow is visible.

7

Put the plastic bag into a screw top secured plastic bottle and draw an arrow with the permanent marker pen to indicate the top of the container and to ensure it is packed and handled in the upright position.

Put tissue or absorbent material like cotton wool around the plastic bag to maintain samples in upright position in bottle and contain a leak if one should occur.

Source: Paul Bloxham/WHO

Sample transport (external)

- *Patient specimens* from suspected or confirmed cases should be transported as UN3373, “Biological Substance Category B”.

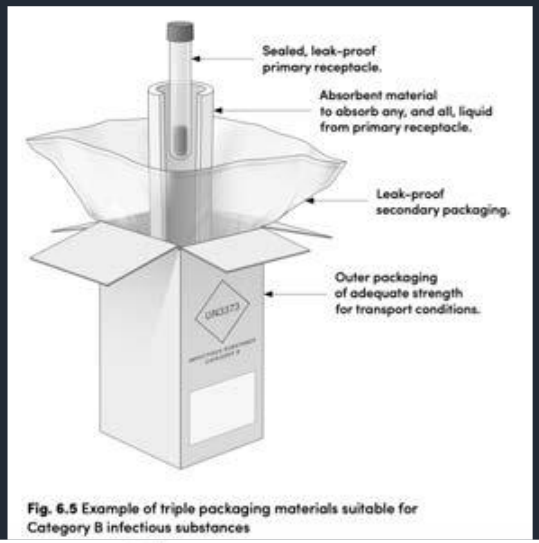


Fig. 6.5 Example of triple packaging materials suitable for Category B infectious substances

- ***Viral cultures or isolates*** should be transported as Category A UN2814, “infectious substance, affecting humans”

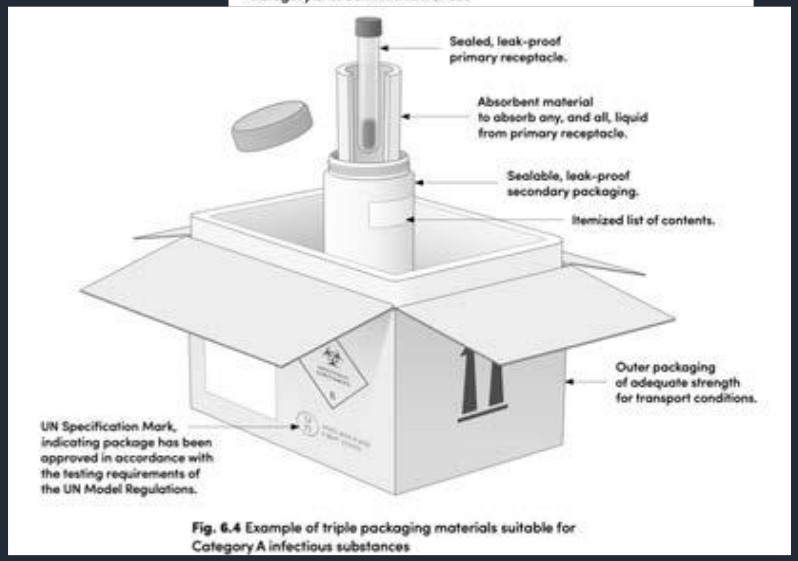


Fig. 6.4 Example of triple packaging materials suitable for Category A infectious substances

Source: WHO laboratory biosafety manual 4th Ed.

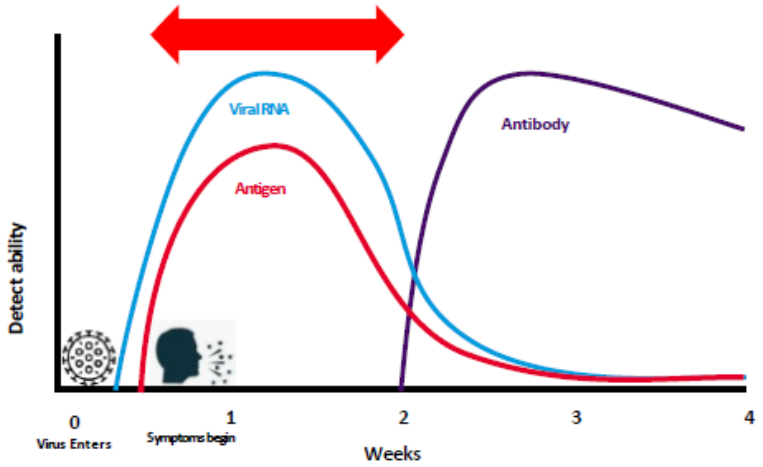
When to test for COVID antigen?

Suggested Use Cases for Ag (FIND)[1]

- Ag tests are useful for detection of COVID-19 active infection.
- Ag RDTs should be prioritized for case management to enable decentralized testing,
- Especially when access to PCR testing is limited
- Triage suspect cases
- Confirm active infection
- Contact tracing

Important considerations:

- Only accurate in initial phase of infection
- Simple
- Rapid
- Affordable
- Accurate



Sethuraman, N., Jeremiah, SS., Ryo, A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. 6 May 2020. doi: 10.1001/jama.2020.8259
Theel ES, The role of antibody testing for SARS-CoV-2: is there one? J Clin Microbiol 58:e00797-20. 2020. https://doi.org/10.1128/JCM.00797-20.

1. FIND Rapid Diagnostic Tests for COVID-19, 18 May 2020. https://www.finddx.org/wp-content/uploads/2020/05/FIND_COVID-19_RDTs_18.05.2020.pdf

Point of Care (PoC) and near-POC Assays

including antigen-detecting RDTs (Ag-RDT)

(No nucleic acid extraction)

- Good Microbiological Practice and Procedure (GMPP)
- Appropriate PPE
- Staff Competence
- May be performed on bench (outside a lab)
  - Well-ventilated area (see the following slides)
  - On absorbent towel or diaper
  - Free of clutter
- Optional
  - Biosafety cabinet/glove box
  - Use primary containment if readily available

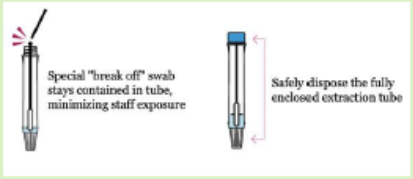
https://www.fda.gov/media/134922/download

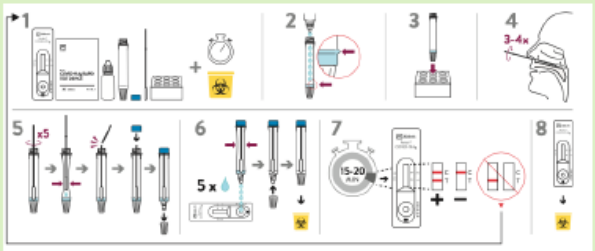
All COVID Ag-RDT can be processed on the open bench in a well ventilated area

No need to use biological safety cabinet

Closed system

Panbio™ COVID-19 Ag RAPID TEST DEVICE (NASOPHARYNGEAL)





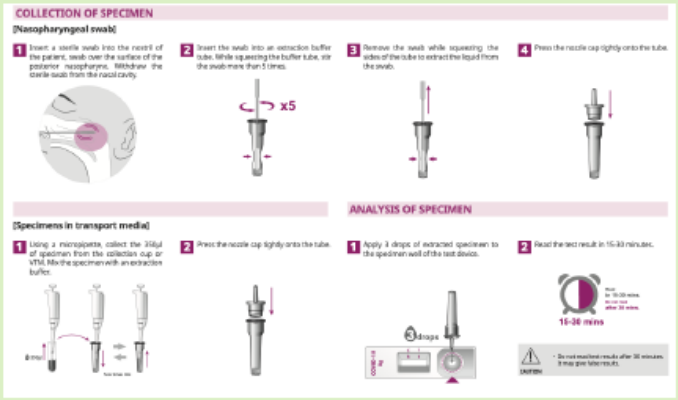
EN

STANDARD Q

COVID-19 Ag

STANDARD™ Q COVID-19 Ag Test

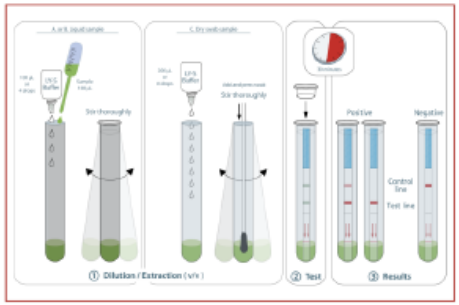
SD BIOSENSOR



Semi-closed system

GORIS BioConcept

COVID-19 Ag Respi-Strip



Wait for aerosols to settle following extraction – 5 mins

Note: Test not listed under WHO EUL (Emergency Use Listing)

Ventilation

The movement of fresh air around a closed space, or the system that does this

Types

- Natural:

Purpose-built, building openings (windows, doors, whirlybirds, chimneys, etc.)

- Assisted (mixed mode):

Relies on natural driving forces to provide the desired (design) flow rate.

- Mechanical- Fans drive mechanical ventilation.

Installed in windows, walls, air ducts

Management decides the type of lab ventilation based on suitability and availability

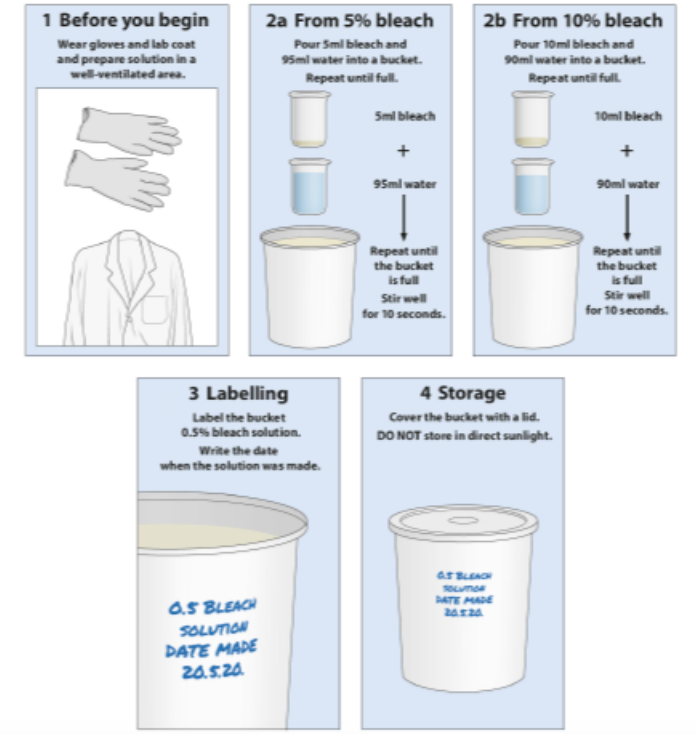
https://medicalguidelines.msf.org/viewport/TUB/latest/appendix-18-advantages-and-disadvantages-of-ventilation-techniques-20324472.html

Use appropriate disinfectants

- COVID-19 virus is susceptible to disinfectants with proven activity against enveloped viruses
- Beware of Bleach – It will produce toxic gases in contact with GITC lysis buffers
  - **Sodium hypochlorite (bleach; for example, 1000 parts per million [ppm] (0.1%) for general surface disinfection and 10000 ppm (1%) for disinfection of sample spills)**

DO NOT use bleach in areas where lysis buffer, Trizol or solutions containing thiocyanate salts have been used. The mixing of sodium hypochlorite in bleach with the thiocyanate salts in lysis buffer will produce toxic gas.
USE 75% ETHANOL INSTEAD.

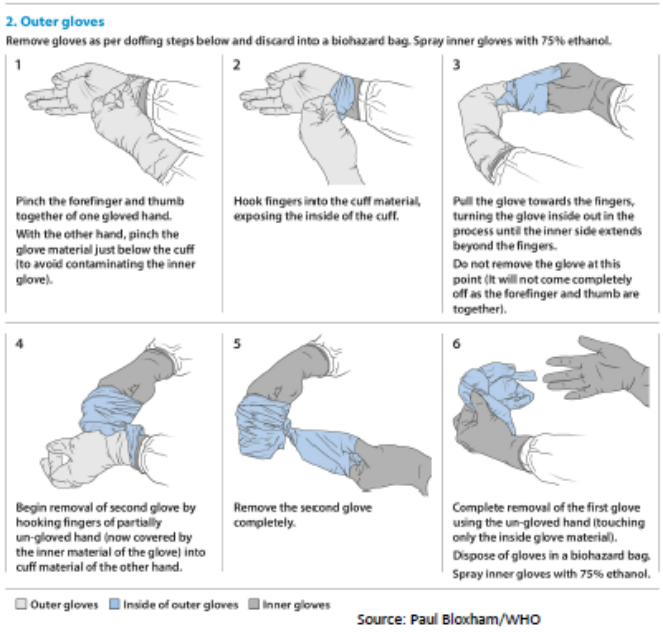
- Alternatives
  - 75% ethanol;
  - 0.5% hydrogen peroxide;
  - Quaternary ammonium compounds;
  - Phenolic compounds;
  - Note: Other biocidal agents such as 0.05–0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate can be less effective.
- **Note:**
  - Contact time (for example, 10 minutes),
  - Concentration of the active ingredient
  - Shelf-life and Expiry date

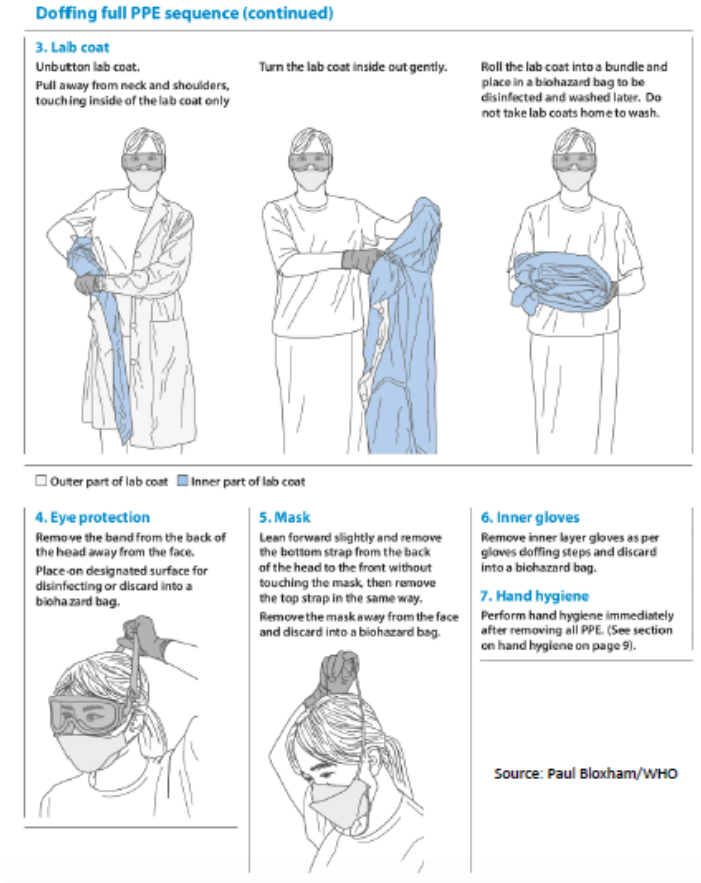


Source: Paul Bloxham/WHO

Completion of activities: PPE doffing

- Ensure that staff are trained in PPE removal to prevent self-contamination.
- Frequent hand hygiene





Note: For illustration purposes – double gloves not recommended for SARS-CoV-2 testing

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Questions?

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